

EXHIBIT

“F”

**IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION**

**IN RE: ETHICON, INC., PELVIC REPAIR
SYSTEM PRODUCTS LIABILITY LITIGATION**

**Master File No. 2:12-MD-02327
MDL 2327**

THIS DOCUMENT RELATES TO:
Kathleen Hahn v. Ethicon, Inc., et al.
2:12-cv-04364

HON. JOSEPH R. GOODWIN

RULE 26 EXPERT REPORT OF DR. WILLIAM PORTER, M.D.

A. Qualifications and Background.

My name is William Edward Porter, M.D. I received a bachelor's degree in biology at the University of Michigan located in Ann Arbor, MI. I then went on and obtained a medical degree from the Wayne State University located in Detroit, MI. I subsequently completed a residency in obstetrics and gynecology at the University of Cincinnati and an American Board of Obstetrics and Gynecology certified three-year fellowship in Female Pelvic Medicine and Reconstructive Surgery (FPMRS) at the University of Tennessee Medical Center located in Memphis, Tennessee. I am one of the first ABOG Certified Physicians in the United States in the Field of (FPMRS). I served as a reviewer for the International Urogynecology Journal (2003 to 2006). I am currently a journal reviewer for Female Pelvic Medicine & Reconstructive Surgery. I serve on the American Urogynecology Society Coding Committee (2012 to 2016). I have lectured locally, nationally, and internationally on many subjects in the field of urogynecology and reconstructive pelvic surgery, including pelvic organ prolapse and urinary incontinence. I have taught at many medical device industry sponsored labs, the purpose of which has been to instruct other surgeons on the proper use of surgical devices and tools to treat pelvic organ prolapse and stress incontinence. I have also worked as a consultant to many medical device companies in developing and validating new products in the pelvic floor space.

I am trained extensively and practice exclusively in the field of pelvic medicine. This field encompasses pelvic organ prolapse, urinary incontinence, fecal incontinence, pelvic pain and pelvic floor dysfunction. Over the past 14 years post residency, I have performed nearly

3,000 pubovaginal slings (synthetic and xenographic) and fascia latta bladder neck slings. I have performed several thousand vaginal repairs for pelvic organ prolapse using native tissue, allograph, xenograph or synthetic augmented repairs. In the same regard I have also removed slings and mesh complicated surgeries (erosion and/ extrusion).

I have been specifically trained to use pelvic organ products (slings, graphs and mesh kits) by the following companies: C. R. Bard, Boston Scientific, Mentor, Cook Medical, Gynecare, American Medical System and Coloplast. I did complete any training required by said companies. I have been a trained proctor for the following companies: C.R. Bard, Boston Scientific, Mentor, Cook Medical, Gynecare and Coloplast. I have specifically treated female patients with the TVT mid-urethral sling.

Based upon my work as a urogynecologist (FPMRS), I am familiar with the medical complications that are generally associated with mesh repair surgery, and I am experienced in the recognition, diagnosis and treatment of patients suffering from complications caused by pelvic repair mesh implants and mid-urethral slings. The focus of my evaluation is the role that the TVT played in causing injury to Ms. Hahn. The most common mesh-related complications are pelvic pain, scarring in the vagina and pelvic floor, pain into the legs and thighs, dyspareunia, chronic inflammation of tissue, chronic vaginal discharge or bleeding, scar bands or scar plates in the vagina, vaginal shortening or stenosis, erosion of mesh into tissues or organs, and nerve entrapment. In diagnosing and treating patients with mesh related complications, I often determine the likely cause of the patient's complications based upon a differential diagnosis, which typically includes a physical and history and a review of her medical records and other information about the patient.

In formulating the opinions set forth in this report I have relied on my personal knowledge, education and training, prior experience in treating stress urinary incontinence, medical literature, and a review of relevant medical records pertaining to Ms. Hahn. All of my opinions are true and correct to the best of my knowledge. I do reserve the right to supplement this report and my opinions if additional information becomes available (reports, discovery, articles or other relevant information). I also reserve the right to perform a physical examination on Ms. Hahn.

B. Summary of Materials Reviewed.

I have reviewed the following medical records and depositions with accompanying exhibits pertaining to Kathleen Hahn:

Avera McKennan Hospital

Sanford USD Medical Center f/k/a Sioux Valley Hospital

Sanford Clinic Adult Medicine

Sanford Female Pelvic Medicine and Reconstructive Surgery Clinic

Deposition of Kathleen Hahn

Plaintiff Profile Form and Plaintiff Fact Sheet of Kathleen Hahn

C. Summary of Medical Facts related to Kathleen Hahn

DOB: 6/2/1957

Past Surgical History

Tubal Ligation, Sclerotherapy, Uterine Ablation, Bladder Instillations

Past Medical History

Obesity, Hypothyroidism, Urge Incontinence, Interstitial Cystitis, High Cholesterol, Gallstone, Renal Cyst

Social

No smoking

Medications

Ditropan, Synthroid

Deposition

She reports constant pain in her right pelvic area. She reports dyspareunia as well as vaginal bleeding. She reports that she had retention and the sling removed to help her urinate. She also reports dyspareunia.

2/18/2003

She had a normal pelvic examination. She was given Detrol.

5/13/2004 She reports urinary incontinence that has increased for the past 2 years. She will start Estrin and Detrol.

6/1/2004

She underwent a TVT for stress incontinence.

4/4/2005

She was using Detrol/Ditropan for her urinary issues. She did well initially well after her sling and developed urgency and frequency 6 months after her surgery.

6/30/2005

She was treated for Interstitial Cystitis, urgency and frequency with cystoscopy and Hydrodistension. She was prescribed Elmiron and Elavil

7/7/2005 She had cystoscopy and Hydrodistension. Her bladder was filled to 800 ml. She had glomerulations that is consistent with IC

5/3/2006

She is very angry regarding about her urinary culture that shows contamination. She feels very symptomatic and believes she has an UTI. She was offered an Elmiron cocktail, but she declines any other treatments.

4/12/2006

She had a normal pelvic examination

5/3/2006 She returns after being treated for multiple UTIs by her primary care doctor. She feels that she cannot clear her infections. She is not having urinary incontinence. She feels her IC are well controlled.

4/16/2007

She has recurrent E.Coli urinary tract infections. She was treated with Cipro.

9/20/2007 She had multiple UTIs with Proteus and E. Coli as one of the isolates. She feels that she is not improving. A CT scan was ordered. She will continue Macrobid suppression.

12/4/2007 She underwent cystoscopy for recurrent UTI. She will continue Macrobid and stop Elmiron as she is doing better.

12/21/2007

She was seen for recurrent UTIs. She was placed on daily Macrobid.

4/21/2008

She has a history of Interstitial Cystitis and recurrent UTIs. Her pelvic examination was normal.

5/8/2008

Her urodynamics showed a slow flow of 3 ml/s on average and a 17 ml/s max. She had a post void residual of 630 ml. She was scheduled for a sling release and Urethrolisis.

6/30/2008

Her retention had resolved and she has some recurrent stress incontinence.

1/22/2010

Uterine ablation/Novasure

3/11/2010

She had her sling removed on 5/16/2008 for urinary retention and obstructed voiding. She did well after her surgery. She reports over the past few months that her UTIs have recurred.

4/1/2010

She was seen by Dr Benson. He felt her IC was managed with bladder instillations.

10/24/2011

She has an IC flare as well as rectocele.

5/14/2012

She switched from Ditropan to Toviaz.

3/4/2013

She reports that her rectocele has become more symptomatic with stool trapping. She has no pain on exam.

3/27/2013

She underwent a TVT sling, posterior repair and perineoplasty.

5/14/2013

She is s/p perineoplasty, TVT and cystoscopy on 3/27/2013

8/14/2015

She has chronic overactive bladder and Interstitial Cystitis.

12/7/2015

Botox injection

D. Methodology and Analysis.

In determining the cause of a specific injury, it is customary to “rule in” potential causes of the injury, and then by process of elimination, to “rule out” the least likely causes to arrive at the most likely cause. This process is known as differential diagnosis, or differential etiology, and it is a well-established and universally accepted methodology for determining the cause of injuries employed by physicians throughout the United States. I often determine the cause of a patient’s complications based upon an interview with the patient, a review of her medical records or knowledge of her prior medical history. I have used that methodology in arriving at my opinions in the case.

As the vagina is a cleaned contaminated area, there is no way to completely eliminate bacteria from the surgical site. Implantation though this dirty field could allow bacteria to attach. These bacteria then can attach to the mesh and secrete a biofilm or a polysaccharide slime excreted by the bacteria. This slime could prevent the host defensive mechanism from clearing the infection. (Edmiston). This tissue response can contribute to the cause of vaginal pain, pelvic pain and chronic inflammation. This chronic inflammation/infection could be a source of pain. This chronic inflammation/infection could be a source of an erosion, vaginal discharge and possible UTI’s. Dr. Daniel Elliott in his general expert report suggested the mesh creates a foreign body reaction and a chronic inflammatory response that can lead to chronic pain in the patient. The body’s foreign body response to the mesh can cause a severe and chronic inflammatory reaction leading to excessive scarring in and around the mesh. Dr. Bruce Rosenzweig of the general expert witness group suggests that mesh degrades over time and causes a chronic foreign body reaction, fibrotic bridging, mesh contracture/shrinkage, fraying, particle loss, roping and curling of the mesh contributing to pain. Ethicon’s Daniel Burkley, a Principal Scientist has testified that polypropylene mesh in human beings is subject to some degree of surface degradation

In considering the cause of the vaginal pain and urinary retention suffered by Kathleen Hahn. Her TVT sling contributed to her urinary retention and vaginal scarring. Dr. Rosenzweig’s suggesting that the chronic inflammation is causing a mesh contracture which could lead to urinary retention. Even after the removal of first sling she underwent another sling procedure.

The next step in my analysis was to rule out other potential causes. I did consider other potential causes including post-op scarring and granulation tissue from tubal ligation. I also considered other factors in her history including her previous pelvic surgery. She is compounded by interstitial cystitis, prior recurrent urinary tract infections and previous surgeries. I considered each of these other risks for her pain and dyspareunia and I concluded that they could not be ruled out as a source of her vaginal pain by Kathleen Hahn.


Additionally, it is my opinion to a reasonable degree of medical and scientific certainty, based on my background, education, training and experience, that Kathleen Hahn treating physicians who implanted met the standard of care during implantation of the device. I found no evidence of surgical error or deviation from the requisite procedural steps. Further, after reviewing the operative reports, I see no evidence of any surgical complications.

E. Conclusion.

Based on the foregoing analysis, and based on my education, training and knowledge, it is my opinion to a reasonable degree of medical probability that the cause of Ms. Hahn's urinary retention to her TVT Mesh Implant. This pain could be related to what Dr. Elliott described as a chronic inflammation around the mesh.

I have the right to supplement and amend this opinion should additional factual information be forwarded to me that I did not have available at the time this opinion is submitted.

Dated this the 17th day of January 2017



William Porter, M.D.